

REQUEST FOR RECONSIDERATION

A. Status of the Claims

Claims 1-100 were filed with the application on June 23, 2000. Claims 1-71, 74-77, 80-83, 85, 97 and 92-93 were canceled and claims 78, 84, 86, 88-91, 94, 95, and 100 were amended in a Preliminary Amendment filed concurrently with the application. Claims 100-114 were added in a Supplemental Preliminary Amendment, mailed in the case on November 1, 2001.

Claims 72, 73, 78, 79, 84, 86, 88-91 and 94-110 were indicated in the first Office Action as pending in the case. It is thus believed by Applicants that the Examiner had renumbered claims 100-114 to 96-110, due to failure to use claim numbers 96-99 in the application as filed and in subsequent Preliminary Amendments. Added claims 100-114 have thus been renumbered to 96-110.

Claims 72-73, 78-79, 84, 86, 88-91, 94-110 were pending at the time of the final Office Action mailed in the case on September 27, 2002 and were finally rejected. The finality was subsequently withdrawn.

The Action states that Appendix A of the amendment filed 6/19/02 cancelled claim 94, but the amendment did not include the amendment and thus the claim is now pending. The claim has been cancelled herein to clarify the record. Claims 72-73, 78-79, 84, 86, 88-91 and 95-110 are pending and presented for reconsideration.

B. Status of the Priority Claim

The Action states that Applicants have not complied with the requirements to obtain the priority of the previous application because the priority information was not inserted in the specification. Specifically, it was stated that application serial number 08/763,704 was not cited in the specification.

In response, Applicants note that the Preliminary Amendment filed concurrently with the patent application on June 23, 2000 amended the specification to recite the priority information. All requirements for claiming the priority of this application have been met and an indication to this effect is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects Claims 72-73, 78-79, 84, 86, 88-91 and 94-110 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Applicant regards as the invention.

(1) The action states that “augmented” is unclear in that it has not been defined and it is not clear if this indicates incorporation of a nucleic acid into the genome. Applicants traverse.

The meaning of the term is clear from the language of the claim. Claim terms must be viewed in the context of the claim in which they are found. In the claim, a fertile transgenic *Zea mays* plant is recited “the genome of which is stably augmented by a preselected DNA sequence.” The claim further specifies that “said preselected DNA sequence is transmitted through a complete normal sexual cycle of the transgenic plant to the next generation.” In view of the claim language, the only reasonable interpretation is that augmented refers to genetic transformation in the genome. Augmented further defines “genome” in the claim, thus

interpretations excluding involvement of the genome may not be made. The claim further specifies that the preselected DNA is transmitted through a sexual cycle and that the genome is "stably augmented." This also indicates stable transformation in the genome. The term as used in the claim is thus fully definite and removal of the rejection is respectfully requested.

(2) The Action rejects the use of the term "preselected" as indefinite because it has not been defined. In response, Applicants note that the term has a well known meaning in the art. Applicants direct the Examiner to the online version of the Merriam Webster® dictionary (<http://www.m-w.com/cgi-bin/dictionary>), which gives the definition of the present tense of preselected, preselect, as being "to choose in advance usually on the basis of a particular criterion." (See Exhibit 1) The dictionary meaning demonstrates the well known meaning of the term. There is nothing indefinite in the use of a term having a well known meaning in the art. Removal of the rejection is thus respectfully requested.

(3) The Action states that "substantially identical" in claim 72 has not been defined. In response, it is noted that the term "substantially identical" is defined in the specification at page 12, lines 11-24. The use of the term in the claims is thus not indefinite. Additionally, the claim is further defined by the language of the claim. For example, claim 72 reads as follows:

A fertile transgenic *Zea mays* plant having an increased starch content, the genome of which is stably augmented by a preselected DNA sequence encoding an RNA molecule which is **substantially identical**, or complementary, to an mRNA encoding a 19kD or a 22kD α -zein plant seed storage protein, wherein the preselected DNA sequence is expressed in the cells of the transgenic plant in an amount sufficient to decrease the amount of said seed storage protein and increase starch content in the cells of a plant which only differ from the cells of said transgenic plant in that said preselected DNA sequence is absent, and wherein said preselected DNA sequence is transmitted through a complete normal sexual cycle of the transgenic plant to the next generation.

(emphasis added)

As can be seen, the claim indicates that expression of the preselected DNA sequence results in a decrease of the amount of seed storage protein and increase starch content in the cells

of a plant. Thus the meaning of the term to one of skill in the art is clear, *e.g.*, that substantially identical must refer to a preselected DNA sequence encoding an RNA molecule that is sufficiently identical to an mRNA encoding a 19kD or a 22kD α -zein plant seed storage protein to hybridize with the seed storage protein mRNA *in vivo* to cause antisense suppression. This is so because the claim specifies that the preselected DNA sequence is expressed in the cells of the transgenic plant in an amount sufficient to decrease the amount of seed storage protein and increase starch content in the cells of a plant comprising the cell. One of skill in the art would thus fully understand the metes and bounds of the claim.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain the meaning of the claim, 35 U.S.C. § 112, second paragraph, is satisfied. *Id.* In view of the definition in the specification and claim language, the referenced term fully meet this requirement. Removal of the rejection is thus respectfully requested.

(4) The Action rejects claims 88 and 90 for use of the terms “substantially complementary to all or a portion” and “substantially identical to all or a portion.” In particular, it is stated that the recited phrases are vague and unclear and do not specify what portion or percent of the sequence applicants are referring to.

In response, it is noted that the terms “substantially identical” and “substantially complementary” are defined in the specification at page 12, lines 11-24. The use of the terms in the claims is thus not indefinite. Still further, the claims define the terms by indicating that expression of the seed storage protein RNA decreases the amount of seed storage protein. Thus

the meaning of the terms to one of skill in the art is clear, *e.g.*, that substantially identical to or complementary to all or a portion refers to those sequences that are complementary such as to hybridize with the seed storage protein mRNA *in vivo* to cause antisense suppression. Such a sequence could not represent a single homologous base pair, as it is well known to those of skill in the art that in order to form the type of stable complex required for antisense suppression, longer stretches of complementary sequences are required.

As indicated above, the test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Id.* If one skilled in the art is able to ascertain the meaning of the claim, 35 U.S.C. § 112, second paragraph, is satisfied. Given the definition in the specification and claim language, the referenced terms fully meet this requirement. In conclusion, Applicants note that the rejected claims are fully definite in compliance with 35 U.S.C. § 112, second paragraph and removal of the rejections is thus respectfully requested.

(5) It is stated that claim 94 is indefinite for recitation of “a gene which encodes kernel hardness.” In response, it is noted that the claim has been cancelled herein and thus the rejection is moot.

D. Rejections Under 35 U.S.C. §112, First Paragraph – Written Description

The Action newly rejects claims 72-73, 78-79, 84, 86, 88-91, and 94-110 under the first paragraph of 35 U.S.C. §112 as lacking an adequate written description of the claimed invention. Applicants initially note that they are puzzled by the rejection, as essentially the same rejection was issued in the first Office Action, but withdrawn in the final Office Action in view of the response to the first Office Action. The current Action nonetheless reissues the rejection, which

alleges that the specification does not describe the structural characteristics of 19 kD or 22 kD α -zein plant seed storage proteins.

In response, it is first noted that Applicants do not claim 19 kD and 22 kD α -zein plant seed storage protein genes *per se*, as this class of genes was known at the time the application was filed, rather transgenic plants expressing these proteins or methods comprising the use thereof are claimed. The structural features unique to a maize "19 kD and 22 kD α -zein plant seed storage protein" have been fully described in the specification. Accordingly, it can not be said that Applicants lack written description for the terms. For example, the Examiner's attention is directed to FIG. 1 of the application. There shown are functional domains that are conserved and shared among the zeins. Further attention is drawn to pages 1-3 of the application. There, the specification describes the family of known zeins, including 19 kD and 22 kD α -zeins. At page 2, it is indicated, with a citation to Rubenstein (1982), that over 70 genes encoding zein protein have been isolated. Further on page 2, at lines 19-24, functional domains of 19 kD α -zeins are described. The structural characteristics of the 19 kD and 22 kD α -zein plant seed storage proteins have thus been described in full compliance with 35 U.S.C. §112, first paragraph and *Eli Lilly* is inapplicable to the instant situation.

The specification still further describes 19 kD and 22 kD α -zein seed storage proteins in the form of the nucleic acid sequence of the A20 and Z4 cDNAs, respectively. While these sequences are species of 19 kD and 22 kD α -zein protein genes, the species are representative of the genus as evidenced by Marks *et al.* (1985), which is cited at page 5 of the Action. Marks *et al.* demonstrates the common structural characteristics shared among 19 kD and 22 kD α -zeins. For example, in the first sentence of the Abstract of Marks *et al.*, it is indicated that a comparison of the protein and DNA sequences of zein cDNA clones "reveals that they share extensive

sequence homology and probably originated from a common ancestral gene.” In the first paragraph of the Discussion section it is indicated that cDNA sequences among the 19 kD and 22 kD group of α -zein sequences are 75 to 95% and 92% homologous, respectively. Further, Marks *et al.* provides sequence information and comparisons among 19 kD and 22 kD α -zeins. The disclosure of Marks *et al.* thereby demonstrates the shared structural characteristics of the 19 kD and 22 kD α -zein seed storage proteins. Combined with Applicants’ disclosure of the structural characteristics of 19 kD and 22 kD α -zein proteins, this is more than adequate to demonstrate compliance with the written description requirement.

In view of the foregoing, Applicants assert that the written description requirement has been fully satisfied. Removal of the rejection under 35 U.S.C. §112, first paragraph is thus respectfully requested.

E. Rejections Under 35 U.S.C. §112, First Paragraph - Enablement

Claims 72-73, 78-79, 84, 86, 88-91 and 94-110 remain rejected under the first paragraph of 35 U.S.C. §112 as allegedly not being enabled by the specification. In particular, the Action alleges that the specification does not teach one of skill how to increase the starch content or starch extractability or kernel hardness of seeds. It is stated that the specification only teaches how to make maize seeds with decreased amounts of the amino acid leucine and increased lysine by transforming *Zea mays* plants with SEQ ID NOs: 1 and 2 operably linked to a Z10 promoter. Applicants respectfully traverse.

Applicants submit that no basis has been provided to doubt the enablement of the claims and further that enablement has been affirmatively demonstrated. The current Action attempts to support the rejection by citing Coleman *et al.* (1997). Although the Action appears to drop the

reference of Marks *et al.* (1985), this was also cited in the enablement rejection in the first Office Action. As set forth below, both of these references affirmatively *demonstrate* the enablement of the invention.

Coleman *et al.* was cited as showing that high-lysine mutants exhibiting a reduction of α -zein content were “concomitant with an inferior endosperm quality.” It was thus suggested that, because of the supposedly inferior endosperm quality, “reducing the α -zein protein content of maize seeds using the strategy of Applicants, will not increase the starch content or starch extractability of maize seeds.” However, the reference does the very opposite and demonstrates the enablement of the claims. This “inferior” endosperm is in fact a *soft and starchy endosperm*. (See Coleman, p. 7094, paragraph 2). The reference therefore shows the direct correlation between increased lysine, decreased α -zein and soft and starchy endosperm. The first Office Action acknowledges this on page 5.¹ Demonstration of this correlation supports enablement, given that the Action already acknowledged that Applicants have demonstrated enablement for increasing lysine. The fact that Coleman *et al.* also demonstrated successful expression of a 24 kDa α -zein gene to induce the mutant phenotype provides still further evidence of enablement of the instant claims.

It is additionally noted that whether the endosperm is subjectively “inferior” or not is irrelevant to enablement. What is considered inferior for a plant used for one purpose, for example, for human consumption, is not necessarily the same as for a plant used for production of corn starch. Further, an “inferior” endosperm does not equate to an inability to increase starch content or extractability, as described in Coleman *et al.*

¹ See middle paragraph: “Two ‘high –lysine’ mutants were identified, opaque2 (o2) and floury2 (fl2) which have a *higher lysine content due to a reduction in the α -zein protein content* of the endosperm.”

The other reference cited in the first Office Action, but apparently dropped for the current Action, also demonstrates enablement. Marks *et al.* (1985), was initially cited as indicating that there are many different forms of 19 kD and 22 kD α -zeins with divergent and unpredictable functions. However, this reference also *supports* the enablement of the invention. Marks *et al.* states in the abstract that:

A comparison of the DNA and protein sequences of a group of zein cDNA clones reveals that they ***share extensive sequence homology and probably originated from a common ancestral gene***. A comparison of clones corresponding to Mr 22,000 polypeptides shows that they are 92% homologous, while five clones corresponding to Mr 19,000 zein vary in homology from 75 to 95%. (emphasis added)

Marks *et al.*, therefore, demonstrates the common structural characteristics shared among 19 kD and 22 kD α -zeins. In the first paragraph of the Discussion section of Marks *et al.*, it is indicated that cDNA sequences among the 19 kD and 22 kD group of α -zein sequences are 75 to 95% and 92% homologous, respectively. Further, Marks *et al.* provides sequence information and comparisons among 19 kD and 22 kD α -zeins. The disclosure of Marks *et al.* thereby demonstrates the shared structural characteristics of the 19 kD and 22 kD α -zein seed storage proteins.

No basis has been provided by the Action to indicate that different isoforms have "divergent functions." The high degree of homology and indicated common ancestor among zeins strongly contradicts this assertion. Additionally, there is no support in the Marks *et al.* reference for the contention that any of the mRNA isoforms described encode proteins other than zeins, the function of which is that of a seed storage protein. The reference, therefore, indicates the shared original and conserved structure of the 19 kD and 22 kD α -zein plant seed storage proteins.

The rejection adds citation to the reference of Moonan (2002). The reference is alleged to show that sugarcane viral protection using less than 100% sequence identity resulted in "inferior viral protection." Applicants note however that this is irrelevant to enablement of the current claims. First, this was sugarcane, not maize as in the instant case, thus there is no showing how this is relevant to the instant claims. Second, what is subjectively "inferior" has absolutely nothing to do with enablement. Enablement concerns teaching one of skill in the art how to make and use the claimed invention, not make and use something that is subjectively superior. Indeed, that statement cited in the Action demonstrates that viral protection *was achieved*, but was apparently somehow subjectively inferior. Again, as long as one of skill in the art can make and use the invention, it is irrelevant if an invention is "inferior" to other techniques that may be available. Finally, the cited reference has to do with viral capsid expression to obtain viral resistance. Again, there is absolutely no basis provided to analogize this to the current case. The claims involve alteration of function of an endogenous maize gene, whereas viral suppression has to do with infection from an external pathogen. The scientific principles are entirely different than for the claimed invention. Applicants do not claim viral resistance. No basis has therefore been provided to draw any analogies between these technologies.

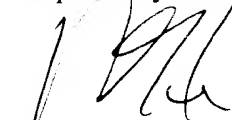
Further evidence of enablement of the claims is provided at page 83 of the specification. There it is described that endosperm cells in a maize kernel are made up primarily of large starch granules and protein sequestered in protein bodies. It is shown that a reduction in the number of protein bodies in endosperm cells derived from a transformant produced using a zein antisense construct was achieved. This was shown by light microscopy and the results given in FIG. 9. As can be seen in the figure, the results demonstrated a decrease in the amount of seed storage protein and therefore an increase in the relative starch content of the kernel.

In conclusion, the Action has failed to set forth any basis for doubting the enablement of the claims. Applicants have further affirmatively set forth evidence of the enablement of the claims that has not been contradicted by the Action. In view of the foregoing, removal of the rejection under 35 U.S.C. §112, first paragraph is thus respectfully requested.

F. Conclusion

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Pronunciation: "prE-s&- 'lekt

Function: *transitive verb*

Date: circa 1859

: to choose in advance usually on the basis of a particular criterion

- **pre·se·lec·tion** ◀ /- 'lek-sh&n/ *noun*

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\&\ as **e** in **kitten**

\&r\ as **ur/er** in **further**

\a\ as **a** in **ash**

\A\ as **a** in **ace**

\e\ as **e** in **bet**

\E\ as **ea** in **easy**

\g\ as **g** in **go**

\i\ as **i** in **hit**

\I\ as **i** in **ice**

\o\ as **aw** in **law**

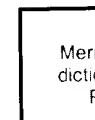
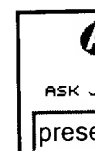
\oi\ as **oy** in **boy**

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